

Attorney Docket No.: KBI-0022  
Inventors: Ranganathan, Natarajan  
Serial No.: 10/803,211  
Filing Date: March 18, 2004  
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#### REMARKS

Claims 1, 2, and 4 are pending in the instant application. Claims 1, 2, and 4 have been rejected. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

#### I. Rejection of Claims Under 35 U.S.C. §112

Claims 1, 2, and 4 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, claim 1 is rejected for lacking sufficient antecedent basis for "said probiotic bacteria". Applicant respectfully traverses this rejection.

Claim 1 recites a composition for augmenting kidney function in a subject comprising *Lactobacillus acidophilus*, *Streptococcus thermophilus*, and *Bifidobacterium longum* probiotic bacteria wherein said probiotic bacteria are in an amount ranging from  $10^9$  to  $10^{11}$  colony forming units and reduce creatinine and BUN levels in the subject. Accordingly, antecedent basis for "said probiotic bacteria" exists in the claim as written. Reconsideration and withdrawal of this rejection is therefore respectfully requested.

#### II. Rejection of Claims under 35 U.S.C. §103

Claims 1, 2 and 4 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy et al. (U.S. Patent No. 6,080,401). The Examiner suggests that Reddy et al. teach compositions for augmenting kidney function comprising *L. acidophilus*, *S. thermophilus*, and *B. longum* wherein the bacteria are present at  $10^9$  to  $10^{11}$  and reduce creatine and BUN levels in

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the subject, and wherein the composition further comprises a gelatin coating and at least one vitamin and one mineral component. It is suggested that while Reddy et al. not teach the claimed amounts of each bacteria, Reddy et al. teach the compositions with varying amounts of probiotics (examples). The Examiner suggests that the amount of probiotic is recognized as a result-effective variable and it would have been well within the preview of one of ordinary skill to optimize the effect amount of the probiotic bacteria of Reddy et al. with a reasonable expectation of successfully obtaining the effective nutritional composition. Moreover, it is suggested that while Reddy et al. do not teach gelatin coating, this reference teaches capsules and capsules refer to pills in the form of small rounded gelatinous containers with medicine inside. Applicant respectfully traverses this rejection.

Reddy et al. teach that the speed of treatment using herbal medicines can be improved by combining the herbal medicine with probiotic microorganisms (see column 3, lines 54-67). In particular, Example 1 (column 15, lines 64-67) of this reference teaches that in a composition containing *L. acidophilus* typically ranging between 0.1 to 400 mg, amounts of *L. acidophilus* "as low as 0.1 mg used with herbs (435 mg), had a pronounced effect in accelerating the beneficial results of herbal activity." Further, Example 3 (column 20, lines 15-18) of Reddy et al. teaches that in a composition containing *L. sporogenes* typically ranging between of 0.01 to 300 mg, *L. sporogenes* showed a significant drug boosting effect "when used in quantities as low as 0.01 mg with 625 mg of herbal preparation. Even the smallest quantity of viable probiotic has a pronounced effect in stimulating the

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herbal preparation". Moreover, Example 6 (column 27, lines 35-38) of this reference teaches that in a composition containing *B. bifidus*, *Pediococcus acidolactici*, *L. acidophilus*, and *L. lactis*, "even a trace amount of probiotic (0.05 mg) added to herbs (500 mg) has a significant effect in enhancing the therapeutic effects of the herbs.". Accordingly, this reference teaches that, within the ranges tested, the lowest bacterial amounts of the typical ranges were sufficient to achieve therapeutic benefit.

In contrast, page 7 (lines 25-30) of the instant specification teaches the criticality of the claimed ranges of each bacterium, namely *L. acidophilus*, *B. longum*, and *S. thermophilus*, for achieving reduced creatinine and BUN levels in a subject so that kidney function is augmented. The particular range of  $10^9$  to  $10^{11}$  cfu for reducing creatinine and BUN levels in a subject is neither taught nor suggested by Reddy et al. In fact, Reddy et al. teach the benefits to be derived from using bacterial amounts at the bottom of the typical ranges disclosed therein, leading the skilled artisan to believe that optimal bacterial amounts for use in compositions are in the range of 0.01 mg to 0.1 mg. The statement in Reddy et al. that "Even the smallest quantity of viable probiotic has a pronounced effect in stimulating the herbal preparation" would discourage one of skill in the art from using  $10^9$  to  $10^{11}$  cfu of bacteria because the cost associated with using such amounts is not essential to achieving therapeutic benefit. In this regard, Reddy et al. teach away from the claimed ranges of the instant invention. See MPEP 2144.05. Accordingly, the present invention can not be held to be obvious in view of Reddy et al. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

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### **III. Double Patenting**

Claims 1, 2, and 4 remain *provisionally* rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/676,622.

Claim 1, 2, and 4 remain *provisionally* rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1, 6, 8, and 10 of copending Application No. 10/689,539.

Applicant respectfully requests that these rejections be held in abeyance until allowable subject matter has been identified in copending Application Nos. 10/676,622 and 10/689,539.

### **IV. Conclusion**

The Applicant believes that the foregoing comprises a full and complete response to the Office Action of record.

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Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



Jane Massey Licata  
Registration No. 32,257

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Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515